



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,041	05/07/2001	Attila Lorincz	2629-4023	1436

7590 07/24/2003  
MORGAN & FINNEGAN, L.L.P.  
345 Park Avenue  
New York, NY 10154-0053

EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/850,041	LORINCZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carla Myers	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

#### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 11, 2003 has been entered.

#### **Claim Rejections - 35 USC § 112**

2. The following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the embodiment of "unmodified" probes. While the specification teaches labeled and unlabeled probes, the specification does not define, nor teach the broader concept of, "unmodified" probes.

**RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traverse this rejection by stating that Webster's dictionary defines the term modified as "to make minor changes in the form and structure of; and to change the form or properties for a definite purpose." Because the term "modified" is defined in the dictionary, Applicants maintain that one would understand that the phrase "unmodified probe" has a commonly known, understood and fixed meaning in the art. However, while the dictionary provides a definition of the term "modified" it does not provide a definition of the phrase "unmodified probe." The specification and art have not set forth what would be encompassed by "minor changes" in a probe.

Applicants further argue that the specification describes "unlabeled and unmodified probes." However, this statement misrepresents the teachings of the specification. The specification in fact discusses only unlabeled probes and does not address or refer to the broader concept of unmodified probes. Applicants state that the specification teaches that probes can be prepared so that they are preferably unlabeled. Based on these teachings in the specification, Applicants conclude that "one reading the instant description understands the meaning of an unmodified probe to be a nucleic acid substance that does not have any changes in form, structure or properties thereof, and that may nevertheless detector identify another substance in a sample." This argument is not convincing because if anything, one reading a specification which discusses only the use of unlabeled probes would consider the phrase "unmodified probe" to mean an unlabeled probe. Again, a probe may be modified with respect to any of its properties

(i.e., its length, its nucleotide sequence, its charge, its molecular weight, etc) and a teaching in the specification limited to only the concept of labeled and unlabeled probes does not provide basis for the much broader concept of unmodified probes. Each of Applicants arguments address the fact that the specification teaches the concept of labeling probes. Applicants have not pointed to any teachings in the specification which would suggest that the specification as originally filed provided basis for the broader concept of modifying the probes in any manner other than by labeling. If Applicants intend for the phrase “unmodified probe” to refer only to a probe that is unlabeled, then the claims should be amended to specifically recite an “unlabelled probe.”

4. Claims 34 and 43-45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 34 is indefinite over the recitation of “unmodified probes”. The specification does not provide a definition for this phrase and there is no art recognized definition for what constitutes an unmodified probe. It is unclear as to whether this is intended to refer to, for example, unlabeled probes, probes which are not protected at their terminus, or probes which are isolated from nature (versus, chemically synthesized probes).

#### **RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traverse this rejection for the reasons stated above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

Applicants further state that there is no requirement for a term used in the claims to match exactly those words used in the disclosure. This argument has been fully considered but is not convincing with respect to the present grounds of rejection because the phrase used in the specification (i.e., probes that are "detectably labeled") does not have a definition of similar meaning or scope to the phrase that Applicants have introduced into the claims (i.e. "unmodified probes"). The specification refers only to labeled and unlabeled probes. While a labeled probe is included within the genus of modified probes, the fact that the art and specification teach labeled probes does not similarly infer that the art and specification provide a clear definition for what is intended to be encompassed by "unmodified probes." A probe is not necessarily a naturally occurring molecule. When one refers to a probe, they often refer to a molecule that has been chemically synthesized. The claims, specification and art do not provide any basis by which one can determine whether a probe has been modified because the claims do not provide a reference point to ascertain whether a probe has been modified. For example, it is unclear as to whether an unmodified probe would include only a probe in its most natural environment, i.e., a naturally occurring DNA molecule present in a cell, or if an unmodified probe can include probes that are chemically synthesized in vitro (such that modifications in their structure and charge are permitted) or if an unmodified probe may be obtained by restriction enzyme digestion (such that modifications in the length, terminal nucleotides and phosphorylation status of the probes are permitted).

B. Claims 43-45 are indefinite over the recitations of "probe comprises HPV 6 and HPV 11" (claim 43), "probe comprises HPV 16..." (claim 44) and "probe contains

one or more HPV types" (claim 44) because it is unclear as to whether the probe contains full genomic copies of the stated HPV types and if the probe includes copies of each of the HPV types (i.e., for claim 44 does the probe contain a copy of each of the genomes of HPV 16, 18 31, 33 and 35?). Clarification of the claims is required.

In the response of April 11, 2003, Applicants do not specifically address this rejection. Accordingly, the rejection is maintained for the reasons of record.

### **Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rashtchian.

Rashtchian (page 1527) teaches a non-radioactive hybridization assay comprising (a) treating a cell sample with sodium hydroxide lysis solution to generate a "hydrolyzed sample of cells"; (b) contacting the hydrolyzed sample of cells with a DNA

probe to form a double-stranded RNA/DNA hybrid between the DNA probe and target RNA; c) capturing the RNA/DNA hybrid onto a solid phase using an immobilized antibody specific for the hybrid; (d) washing to remove unhybridized probe; and (e) detecting the bound hybrid as indicative of the presence of the target RNA. The bound hybrids are detected using a streptavidin-peroxidase reagent. The method of Rashtchian requires the use of the reagents of buffers, which can be used to stabilize biological samples, a DNA probe, a solid support to which an anti-RNA/DNA antibody has been immobilized, and a streptavidin-peroxidase reagent for detecting bound RNA/DNA hybrids. Rashtchian does not teach packaging these reagents into a kit. However, reagent kits for performing diagnostic methods were conventional in the field of molecular biology at the time the invention was made. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents of a buffer, a DNA probe, a solid-support having an anti-RNA/DNA antibody immobilized thereon, and a detection means in a kit for the expected benefits of convenience and cost-effectiveness for practitioners in the art wishing to perform the detection method of Rashtchian.

#### **RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traverse this rejection by stating that Rashtchian teaches use of a biotinylated probe, but does not teach use of an unmodified probe. Applicants argue that any skilled artisan would recognize that a biotin attached to a nucleic acid is a modification of the chemical and structural integrity of the nucleic acid.



This argument is not convincing because, as discussed above, it is unclear as to what is intended to be encompassed by an unmodified probe. The claims do not provide a reference point by which one can determine what constitutes unmodified. The probe of Rashtchian is unmodified in that its nucleic acid sequence has not been altered as compared to the wild-type probe sequence. Thus, with respect to other biotinylated probes, the probe of Rashtchian constitutes an unmodified probe. The claims and specification do not require that the probe is unmodified with reference to an unlabeled/non-biotinylated probe. Since it is unclear as to what constitutes an unmodified probe, the biotinylated probe of Rashtchian is considered to be included by the claimed invention.

6. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashtchian in view of Carrico (U.S. Patent No. 5,200,313).

Rashtchian (page 1527) teaches a non-radioactive hybridization assay comprising (a) treating a cell sample with sodium hydroxide lysis solution to generate a "hydrolyzed sample of cells"; (b) contacting the hydrolyzed sample of cells with a DNA probe to form a double-stranded RNA/DNA hybrid between the DNA probe and target RNA; c) capturing the RNA/DNA hybrid onto a solid phase using an immobilized antibody specific for the hybrid; (d) washing to remove unhybridized probe; and (e) detecting the bound hybrid as indicative of the presence of the target RNA. Rashtchian teaches labeling the probe with biotin and detecting immobilized/bound probe using a streptavidin-peroxidase complex. Rashtchian does not teach using an unlabeled probe or detecting the immobilized probe using an antibody reactive with the RNA/DNA hybrid.

Carrico (col. 2-3) teaches a method for detecting a target nucleic acid wherein the method comprises detecting an immobilized RNA/DNA hybrid using an antibody that specifically reacts with the hybrid. The reference further teaches detecting the antibody bound to the immobilized RNA/DNA complex using a labeled anti-(antibody) antibody. The reference also teaches that the anti-hybrid antibody may be labeled and detected directly (column 10).

In view of the teachings of Carrico, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rashtchian so as to have detected the immobilized RNA/DNA hybrid using an antibody reactive with the RNA/DNA hybrid in order to have achieved the benefits stated by Carrico of obviating the need to label the probe, thereby providing a simpler and more convenient detection method.

With respect to claim 33, modification of the method of Rashtchian as discussed above results in an assay that requires the reagents of buffers, which can be used to stabilize biological samples, an unlabeled/ "unmodified" DNA probe, a solid support to which an anti-RNA/DNA antibody has been immobilized, and a means for detecting bound RNA/DNA hybrids. Rashtchian does not teach packaging these reagents into a kit. However, reagent kits for performing diagnostic methods were conventional in the field of molecular biology at the time the invention was made. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents of a buffer, a unlabeled/ "unmodified" DNA probe, a solid-support having an anti-RNA/DNA antibody immobilized thereon, and a detection

means in a kit for the expected benefits of convenience and cost-effectiveness for practitioners in the art wishing to perform the detection method of Rashtchian.

**RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traverse this rejection by stating that “as previously described an ‘unmodified nucleic acid probe’ is a nucleic acid that has not been altered or modified, physically, structurally or chemically.” However, this is only the definition for an unmodified probe that Applicants have incorporated into their response. This is not an art recognized definition of the phrase “unmodified probe” or a meaning that was clearly set forth in the specification as originally filed. Accordingly, such a limitation for the phrase “unmodified probe” has not been read into the claims. Applicants argue that immobilization of a probe alters its physical properties. However, even if one considered that immobilization of a probe meant that the probe was modified, prior to the probe being immobilized, its properties have not been altered. Thus, the teachings of Carrico that the probe is immobilizable does not mean that the probe has been modified. Further, the specification as originally filed does not provide basis for interpreting the claims as being limited to the use of only probes that are not immobilized and which could never be immobilized. Applicants own probes are in fact “immobilizable” since, once the probes are hybridized to a target sequence, the “unmodified probe”/target complex is immobilized onto a solid phase by binding to anti-hybrid antibody. Furthermore, only present claim 33 recites an “unmodified probe.” The remaining claims are inclusive of any type of probe.

Additionally, the present rejection is based on the combined teachings of Rashtchian and Carrico, rather than on the teachings of each reference separately. While Carrico teaches immobilizing probes prior to contacting the probes with the target nucleic acid, the primary reference of Rashtchian teaches the concept of solution hybridization between the probe and the target nucleic acid followed by capture of the resulting hybrid to an anti-hybrid antibody immobilized on a solid support. Carrico was cited for its teachings that a probe/target hybrid can be detected without the need to label the probe. Modification of the method of Rashtchian so as to directly detect the antibody bound to the immobilized RNA/DNA complex using a labeled anti-(antibody) antibody (as taught by Carrico) results in a method in which a probe is utilized that is not itself labeled and which is not itself directly immobilized onto a support at the point in which the probe is hybridized to the target nucleic acid. As discussed in the above rejection, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rashtchian so as to have detected the immobilized RNA/DNA hybrid using an antibody reactive with the RNA/DNA hybrid in order to have achieved the benefits stated by Carrico of obviating the need to label the probe, thereby providing a simpler and more convenient detection method.

**RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traversed this rejection for the same reasons as discussed in paragraph 6 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

7. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashtchian in view of Carrico and further in view of Thompson.

The teachings of Rashtchian and Carrico are presented above. In particular, Rashtchian teaches removing unhybridized probe by performing repeated wash steps but does not teach using an enzyme, such as RNase, to remove unhybridized probe.

However, Thompson et al. (p. 264, column 2) discloses a hybridization assay wherein unhybridized RNA probe is removed from the reaction mixture by treatment with RNase. Thompson (p. 264) states that "in solution hybridization, unreacted probe is usually in vast excess over hybrids. This creates the problem of a background signal arising from non-specific interaction of probe with solid supports used to purify hybrids. Background signals usually determine the sensitivity of an assay. Three general strategies have been employed to accomplish hybrid purification: selective immobilization, nuclease digestion of unhybridized probe, and sandwich hybridization". In view of the disclosure of Thompson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rashtchian so as to have included the step of RNase digestion taught by Thompson for the advantage expressly stated by Thompson of more efficiently removing unhybridized probe, thereby reducing background signal and increasing the overall sensitivity of the detection method.

Secondly, Rashtchian does not teach methods in which 1-500 ng/ml, particularly 75 ng/ml is utilized. However, to determine the optimum concentration of reactants is well within the skill of the art (see *In re Kronig* 190 U.S.P.Q. 425). Furthermore,

Thompson (page 264) teaches that solution hybridization methods should be performed using excess probe. As stated by Thompson, "under these conditions, all targets in a sample can be saturated with probe. The rate of the reaction is dependent upon the concentration of probe, and independent of target concentration, so that all reactions are complete at the same time, regardless of the amount of target present."

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made and well within the skill of the art to have selected and used an effective amount of probe based upon the specific reaction conditions for each sample for the expected benefit of optimizing the effectiveness and sensitivity of the non-radioactive hybridization method.

#### **RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traversed this rejection for the same reasons as discussed in paragraph 6 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

8. Claims 41, 42, 46, 47, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashtchian in view of Carrico and further in view of Longiaru (U.S. Patent No. 5,232,829).

The teachings of Rashtchian and Carrico are presented above. In particular, Rashtchian teaches a method for detecting *Campylobacter* but does not teach applying this method to the detection of HPV, HBV or Chlamydia. However, one of ordinary skill in the art would readily recognize that a nucleic acid technique which detects the presence of a sample nucleic acid via the use of a probe could be applied to the

Art Unit: 1634

detection of any target nucleic acid and thereby would recognize that the method of Rashtchian would be applicable to the detection of any desired target nucleic acid. Furthermore, Carrico teaches that the method disclosed therein of detecting an immobilized probe/target nucleic acid complex with an antibody directed against RNA/DNA hybrids is useful for the detection of any viral or bacterial target sequence (see column 1). Additionally, Longiaru teaches methods for detecting a target nucleic acid and discusses the need to develop assays for the detection of HPV, HBV and Chlamydia (see columns 9-10).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rashtchian in view of Carrico to the detection of HPV, HBV and chlamydia in order to have developed an effective and sensitive means for detecting the presence of these organisms.

Moreover, reagent kits for performing diagnostic methods were conventional in the field of molecular biology at the time the invention was made. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents of a buffer, a probe complementary to HPV, HBV or chlamydia nucleic acids, a solid-support having an anti-RNA/DNA antibody immobilized thereon, and a detection means in a kit for the expected benefits of convenience and cost-effectiveness for practioners in the art wishing to perform the detection method of Rashtchian and wishing to detect the presence of HPV, HBV, or Chlamydia.

**RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traversed this rejection for the same reasons as discussed in paragraph 6 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

9. Claims 41-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rashtchian in view of Carrico and further in view of Herzog (U.S. Patent No. 4,983,728).

The teachings of Rashtchian and Carrico are presented above. In particular, Rashtchian teaches a method for detecting *Campylobacter* but does not teach applying this method to the detection of HPV, particularly HPV 6, 11, 18, 31, 33, 35, 42, 43 or 44. However, one of ordinary skill in the art would readily recognize that a nucleic acid technique which detects the presence of a sample nucleic acid via the use of a probe could be applied to the detection of any target nucleic acid and thereby would recognize that the method of Rashtchian would be applicable to the detection of any desired target nucleic acid. Furthermore, Carrico teaches that the method disclosed therein of detecting an immobilized probe/target nucleic acid complex with an antibody directed against RNA/DNA hybrids is useful for the detection of any viral or bacterial target sequence (see column 1). Additionally, Herzog teaches methods for detecting a target HPV nucleic acid and discusses the need to develop assays for the detection of HPV 6, 11, 16, 18 and 33 (see columns 1 and 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rashtchian in view of Carrico to the detection of HPV 6, 11, 16, 18 and 33 in order to have developed an



Art Unit: 1634

effective and sensitive means for detecting the presence of these HPV types.

Moreover, reagent kits for performing diagnostic methods were conventional in the field of molecular biology at the time the invention was made. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents of a buffer, a probe complementary to HPV 6, 11, 16, 18 or 33 nucleic acids, a solid-support having an anti-RNA/DNA antibody immobilized thereon, and a detection means in a kit for the expected benefits of convenience and cost-effectiveness for practitioners in the art wishing to perform the detection method of Rashtchian and wishing to detect the presence of HPV 6, 11, 16, 18 or 33.

#### **RESPONSE TO ARGUMENTS:**

In the response of April 11, 2003, Applicants traversed this rejection for the same reasons as discussed in paragraph 6 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-

Art Unit: 1634

2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 22, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER